

## **12 KAR 3:037. Additives.**

RELATES TO: KRS 250.501, 250.511, 250.541(1)(a), (b), (c), (d), (e), (f), (j), (2)(c), (d), (e), 21 C.F.R. Parts 70, 71, 73, 74, 80, 81, 82, 501.22, 570.3(1), 570.30, 582, 21 U.S.C. 360(b)

STATUTORY AUTHORITY: KRS 250.571(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.571(1) authorizes the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for efficient enforcement of KRS 250.491 to 250.631. KRS 250.541 defines adulterated commercial feeds and states how they may be adulterated by additives. KRS 250.551(1) and (2) prohibits the manufacturing and distribution of adulterated products as animal feeds. This administrative regulation establishes requirements to ensure that a drug or additive used in pet food is safe and effective for its intended purpose.

Section 1. An artificial color may be used in a pet food if it has been shown to be harmless to pets. The permanent or provisional listing of an artificial color in 21 CFR Part 70, 71, 73, 74, 80, 81, or 82, or 501.22 as safe for use, together with the conditions, limitations, and tolerances, if any, shall be satisfactory evidence that the color is harmless to pets.

Section 2. Before approval of a label and a registration application, the distributor of a pet food, containing an additive including a drug, another special purpose additive, or a nonnutritive additive shall, upon request of the director, submit evidence to prove the safety and efficacy of the pet food if used according to label directions. Satisfactory evidence of the safety and efficacy of a pet food shall be:

- (1) If the pet food contains an additive that conforms to 21 CFR 570.3(1), 570.30, or Part 582; or
- (2) If the pet food is a drug as defined in KRS 250.501(7) and is generally recognized by the Food and Drug Administration as safe and effective for its labeled use or is marketed subject to an application approved by the Food and Drug Administration under 21 USC 360(b).

Section 3. The medicated labeling format recommended by the Association of American Feed Control Officials in its Official Publication shall be used to insure that adequate labeling is provided.

Section 4. Incorporation by Reference. (1) "Official Publication", (1998 Edition), Association of American Feed Control Officials, is incorporated by reference.

(2) This material may be inspected, copied, or obtained at the Division of Regulatory Services, 103 Regulatory Services Building, College of Agriculture, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m. (AES-2 (1973)-PF 7; 1 Ky.R. 1003; eff. 6-11-75; Am. 23 Ky.R. 1618; eff. 1-10-97; 25 Ky.R. 900; 2364; eff. 4-14-99.)